

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

# IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESAL PRICE LITIGATION

MDL No. 1456

Civil Action No. 01-CV-12257-PBS

THIS DOCUMENT RELATES TO:

Judge Patti B. Saris

*State of Montana v. Abbott Labs., Inc., et al.*,  
D. Mont. Cause No. CV-02-09-H-DWM

**SCHERING-PLOUGH CORPORATION'S ANSWER TO THE STATE OF MONTANA'S  
SECOND AMENDED COMPLAINT**

Schering-Plough Corporation (“Schering-Plough”) answers the State of Montana’s Second Amended Complaint (“Amended Complaint”) as follows:

1. The allegations in paragraph 1 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 1.
2. Schering-Plough admits that it is a manufacturer of pharmaceutical products. To the extent the allegations of this Paragraph refer to statutory or regulatory programs, the statutes, regulations and other sources regarding those programs speak for themselves. To the extent that the allegations in paragraph 2 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 2. Schering-Plough denies the remaining allegations in paragraph 2.

3. The allegations in paragraph 3 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 3.

4. The allegations in paragraph 4 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 4.

5. To the extent that the allegations in paragraph 5 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 5. Schering-Plough denies the remaining allegations in paragraph 5.

6. To the extent that the allegations in paragraph 6 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 6. Schering-Plough admits that it reports certain pricing information for its medicines to pharmaceutical industry pricing publications. Schering-Plough denies the remaining allegations in paragraph 6.

7. To the extent that the allegations in paragraph 7 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 7. Schering-Plough denies the remaining allegations in paragraph 7.

8. To the extent that the allegations in paragraph 8 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 8. Schering-Plough denies the remaining allegations in paragraph 8.

9. To the extent that the allegations in paragraph 9 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 9. Schering-Plough denies the remaining allegations in paragraph 9.

10. To the extent that the allegations in paragraph 10 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 10. Schering-Plough denies the remaining allegations in paragraph 10.

11. Plaintiff's "Best Price" claims against Schering-Plough have been dismissed by Court Order. Accordingly, no answer is required.

12. Plaintiff's "Best Price" claims against Schering-Plough have been dismissed by Court Order. Accordingly, no answer is required.

13. To the extent that the allegations in paragraph 13 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 13. Schering-Plough denies the remaining allegations in paragraph 13.

14. To the extent that the allegations in paragraph 14 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 14. Schering-Plough denies the remaining allegations in paragraph 14.

15. To the extent that the allegations in paragraph 15 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a

belief as to the truth or falsity of the allegations in paragraph 15. Schering-Plough denies the remaining allegations in paragraph 15.

16. To the extent that the allegations in paragraph 16 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 16. Schering-Plough denies the remaining allegations in paragraph 16.

17. To the extent that the allegations in paragraph 17 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 17. Schering-Plough denies the remaining allegations in paragraph 17.

18. The allegations in paragraph 18 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 18.

19. The allegations in paragraph 19 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 19.

20. The allegations in paragraph 20 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 20.

21. The allegations in paragraph 21 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 21.

22. The allegations in paragraph 22 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 22.

23. The allegations in paragraph 23 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 23.

24. The allegations in paragraph 24 state legal conclusions as to which no answer is required. To the extent the allegations in paragraph 24 refer to statutes, regulations or other documents, those sources speak for themselves. To the extent that an answer is otherwise required, Schering-Plough denies the allegations in paragraph 24.

25. The allegations in paragraph 25 state legal conclusions as to which no answer is required. To the extent the allegations in paragraph 25 refer to statutes, regulations or other documents, those sources speak for themselves. To the extent that an answer is otherwise required, Schering-Plough denies the allegations in paragraph 25.

26. Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 26.

27. Schering-Plough is without information or belief as to the truth or falsity of the allegations contained in paragraph 27. To the extent an answer is required, Schering-Plough denies the allegations in paragraph 27.

28. Schering-Plough admits the allegations contained in the first sentence of paragraph 28. To the extent that the remaining allegations refer to statutes, regulations or other documents, those sources speak for themselves. Schering-Plough is otherwise without information or belief as to the truth or falsity of the allegations contained in paragraph 28. To

the extent an answer is required, Schering-Plough denies the remaining allegations in paragraph 28.

29. To the extent that the allegations in paragraph 29 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 29. To the extent the allegations in paragraph 29 state legal conclusions as to which no answer is required, no answer is made. To the extent that an answer is otherwise required, Schering-Plough denies the allegations in paragraph 29.

30. To the extent that the allegations in paragraph 30 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 30. Schering-Plough otherwise admits that it transacted business in the State of Montana.

31-96. The allegations contained in paragraphs 31 through 96 refer to parties other than Schering-Plough. To the extent the allegations contained in paragraphs 31 through 96 are deemed to include allegations against Schering-Plough, Schering-Plough denies the allegations.

97. Schering-Plough admits the allegations in the first sentence of paragraph 97. Schering-Plough further admits that its revenues in 2001 totaled \$9.8 billion. Schering-Plough avers that it is a holding company that does not engage in the sale of products. Schering-Plough otherwise admits the allegations in paragraph 97.

98. Schering-Plough avers that Warrick Pharmaceuticals Corporation is a second-tier subsidiary of Schering-Plough. Schering-Plough otherwise admits the allegations in paragraph 98.

99. The allegations in paragraph 99 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 99.

100. Schering-Plough admits the allegations contained in paragraph 100.

101-111. The allegations contained in paragraphs 101 through 111 refer to parties other than Schering-Plough. To the extent the allegations contained in paragraphs 101 through 111 are deemed to include allegations against Schering-Plough, Schering-Plough denies the allegations.

112. The allegations in paragraph 112 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 112.

113-121. To the extent that the allegations in paragraphs 113 through 121 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. To the extent that the allegations in paragraphs 113 through 121 refer to publications and other documents, those documents speak for themselves. To the extent the allegations in paragraphs 113 through 121 state legal conclusions as to which no answer is required, no answer is made. To the extent that an answer is otherwise required, Schering-Plough denies the allegations in paragraphs 113 through 121.

122. Schering-Plough is without information or belief as to the truth or falsity of the allegations contained in paragraph 122. To the extent an answer is required, Schering-Plough denies the allegations in paragraph 122.

123. The allegations in paragraph 123 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 123.

124-131. The allegations in paragraphs 124 through 131 state legal conclusions as to which no answer is required. To the extent that the allegations in paragraphs 124 through 131 refer to publications and other documents, those documents speak for themselves.

132. The allegations in the first and third sentences of paragraph 132 state legal conclusions as to which no answer is required. To the extent an answer is required, Schering-Plough denies the allegations in the first and third sentences of paragraph 132. Schering-Plough denies the allegations in the second sentence of paragraph 132.

133-135. The allegations in paragraphs 133 through 135 state legal conclusions as to which no answer is required. To the extent that the allegations in paragraphs 133 through 135 refer to publications or other documents, those documents speak for themselves.

136-137. Schering-Plough is without information or belief as to the truth or falsity of the allegations contained in paragraphs 136 and 137. To the extent an answer is required, Schering-Plough denies the allegations in paragraphs 136 and 137.

138-140. The allegations in paragraphs 138 through 140 state legal conclusions as to which no answer is required. To the extent that the allegations in paragraphs 138 through 140 refer to publications and other documents, those documents speak for themselves.

141. Schering-Plough is without information or belief as to the truth or falsity of the allegations contained in paragraph 141. To the extent an answer is required, Schering-Plough denies the allegations in paragraph 141.

142-144. Schering-Plough admits the allegations in paragraphs 142 through 144.

145. To the extent that the allegations in paragraph 145 refers to a publication entitled "Medicare Explained," that documents speaks for itself. Schering-Plough is otherwise without information or belief as to the truth or falsity of the allegations contained in paragraph 145.



146. Schering-Plough admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth at 42 C.F.R. § 405.517, which speaks for itself.

147. To the extent the allegations in the first sentence of paragraph 147 are based on an unnamed source, Schering-Plough is without information or belief as to the truth or falsity of those allegations. Schering-Plough otherwise admits that providers of Medicare- and Medicaid-covered products have historically been reimbursed based on AWP published in certain industry compendia.

148. Schering-Plough admits the allegations contained in paragraph 148.

149. Schering-Plough admits the allegations contained in the first sentence of paragraph 149. The allegations contained in the second sentence of paragraph 149 are based on a document, Program Memorandum AB-99-63, which speaks for itself.

150. The allegations contained in paragraph 150 are based on a document, Program Memorandum AB-99-63, which speaks for itself.

151. Schering-Plough admits that it reports certain pricing information for their medicines to pharmaceutical industry pricing publications. To the extent that the allegations in paragraph 151 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. Schering-Plough otherwise denies the allegations contained in paragraph 151.

152-153. Schering-Plough admits the allegations contained in paragraphs 152 and 153.

154-157. To the extent the allegations contained in paragraphs 154 through 157 refer to publications and other sources, those documents speak for themselves. Schering-Plough otherwise denies the allegations in contained in paragraphs 154 through 157.

158. To the extent paragraph 158 is based on statutes, regulations or other sources, those documents speak for themselves. Schering-Plough otherwise admits the allegations contained in paragraph 158.

159. To the extent paragraph 159 is based on statutes, regulations or other sources, those documents speak for themselves. Schering-Plough otherwise admits the allegations contained in paragraph 159.

160. To the extent the allegations contained in paragraph 160 are based on the publication, "Detailed Case Studies," that documents speaks for itself. Schering-Plough is otherwise without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 160.

161. To the extent the allegations contained in paragraph 161 are based on the publication, "Detailed Case Studies," that documents speaks for itself. Schering-Plough is otherwise without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations contained in paragraph 161.

162. To the extent the allegations contained in paragraph 162 are based on statutes, regulations, publications, or other sources, those documents speak for themselves. Schering-Plough otherwise denies the allegations contained in paragraph 162.

163. To the extent the allegations contained in paragraph 163 are based on statutes, regulations, or other sources, those documents speak for themselves. To the extent the allegations in paragraph 163 state legal conclusions, no answer is required. Schering-Plough otherwise denies the allegations contained in paragraph 163.

164. The allegations in paragraph 164 state legal conclusions as to which no answer is required. To the extent that an answer is required, Schering-Plough denies the allegations in paragraph 164.

165. Upon information and belief, Schering-Plough admits the allegations contained in the first two sentences of paragraph 165. Schering-Plough otherwise denies the allegations contained in paragraph 165.

166. To the extent that the allegations in paragraph 166 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. Schering-Plough otherwise denies the allegations contained in paragraph 166.

167. Schering-Plough admits the allegations contained in paragraph 167.

168. To the extent that the allegations in paragraph 168 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. To the extent that the allegations in paragraph 168 refer to publications and other documents, those documents speak for themselves. Schering-Plough otherwise denies the allegations contained in paragraph 168.

169. Schering-Plough denies the allegations contained in paragraph 169.

170-171. The April 2003 OIG report cited in Paragraphs 170 through 171 speaks for itself. Schering-Plough otherwise denies the allegations contained in paragraphs 170 through 171.

172-175. Schering-Plough denies the allegations contained in paragraphs 172-175.

176. Schering-Plough admits that it reports certain pricing information for their medicines to pharmaceutical industry pricing publications. To the extent that the allegations in

paragraph 176 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations.

177-184. To the extent that the allegations in paragraphs 177 through 184 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. Schering-Plough otherwise denies the allegations contained in paragraphs 177 through 184.

185. Schering-Plough denies the allegations contained in paragraph 185.

186. To the extent that the allegations in paragraph 186 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. Schering-Plough otherwise denies the allegations contained in paragraph 186.

187. To the extent that the allegations in paragraph 187 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. To the extent that the allegations in paragraph 187 refer to a federal regulation, that document speaks for itself. Schering-Plough otherwise denies the allegations contained in paragraph 187.

188. Schering-Plough states that the allegations contained in paragraph 188 are based on statutes and regulations, which speak for themselves.

189. To the extent that the allegations in paragraph 189 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. Schering-Plough otherwise denies the allegations contained in paragraph 189.

190. To the extent that the allegations in paragraph 190 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. Schering-Plough otherwise denies the allegations contained in paragraph 190.

191. To the extent that the allegations in paragraph 191 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. Schering-Plough otherwise denies the allegations contained in paragraph 191.

192. Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 192, including the identity of the unnamed “industry consultant” referenced therein.

193. Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 193.

194. Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 194.

195. To the extent that the allegations in paragraph 195 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. Schering-Plough otherwise denies the allegations contained in paragraph 195

196-200. To the extent that the allegations in paragraphs 196 through 200 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. The documents cited in paragraphs

196 through 200 speak for themselves. Schering-Plough otherwise denies the allegations contained in paragraphs 196 through 200.

201-208. To the extent that the allegations in paragraphs 201 through 208 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. Schering-Plough otherwise denies the allegations contained in paragraphs 201 through 208

209. To the extent that the allegations in paragraph 209 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. The document cited in paragraph 209 speaks for itself. Schering-Plough otherwise denies the allegations contained in paragraph 209.

210. Schering-Plough admits that the DOJ and the OIG have been investigating Schering-Plough, among others, for practices relating to the calculation of AWP. Schering-Plough further admits that the United States House of Representatives Committee on Commerce has made requests for documents and information relating to AWP, to which Schering-Plough has responded. To the extent that the allegations in paragraph 210 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 210. Schering-Plough otherwise denies the remaining allegations in paragraph 210.

211-212. To the extent that the allegations in paragraphs 211 through 212 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraphs 211 through 212.

Schering-Plough states that the letter cited in paragraphs 211 through 212 speaks for itself.

213. Schering-Plough admits that the DOJ and the OIG have been investigating Schering-Plough, among others, for practices relating to the calculation of AWP. Schering-Plough further admits that the United States House of Representatives Committee on Commerce has made requests for documents and information relating to AWP, to which Schering-Plough has responded. To the extent that the allegations in paragraph 213 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 213. Schering-Plough otherwise denies the remaining allegations in paragraph 213.

214-215. To the extent that the allegations in paragraphs 214 through 215 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraphs 214 through 215. Schering-Plough otherwise denies the remaining allegations in paragraphs 214 through 215.

216-531. The allegations contained in paragraphs 216 through 531 refer to parties other than Schering-Plough. To the extent the allegations contained in paragraphs 216 through 531 are deemed to include allegations against Schering-Plough, Schering-Plough denies the allegations.

532. Schering-Plough denies the allegations contained in paragraph 532.

533. Schering-Plough denies the allegations contained in paragraph 533.

534. Schering-Plough admits that it communicates with industry compendia concerning AWP for its products. Schering-Plough avers that the document referenced in the second sentence of paragraph 534 speaks for itself. Schering-Plough denies the remaining allegations in paragraph 534.

535. Schering-Plough denies the allegations contained in paragraph 535.

536. The document referenced in the second sentence of paragraph 536 speaks for itself. Schering-Plough denies the remaining allegations in paragraph 536.

537. The document referenced in the second sentence of paragraph 537 speaks for itself. Schering-Plough denies the remaining allegations in paragraph 537.

538. The documents referenced in paragraph 538 speak for themselves. Schering-Plough denies the remaining allegations in paragraph 538.

539. Schering-Plough admits that the published AWP's for most of its drugs were higher than the actual prices provided to wholesalers. To the extent that the allegations in paragraph 539 refer to specific documents, those documents speak for themselves.

540. The documents referenced in paragraph 540 speak for themselves. Schering-Plough denies the remaining allegations in paragraph 540.

541. The documents referenced in paragraph 541 speak for themselves. Schering-Plough denies the remaining allegations in paragraph 541.

542. Schering-Plough denies the allegations contained in paragraph 542.

543. Schering-Plough admits that it has been investigated by the Department of Justice, the Texas Attorney General, the West Virginia Attorney General, California Attorney General, the California Attorney General, the California Bureau of Medi-Cal Fraud and Elder Abuse, the Department of Health and Human Services Office of Inspector General, and the United States Attorney for the District of Massachusetts for practices relating to the calculation of AWP. Schering-Plough otherwise denies the remaining allegations in paragraph 543.

544. Schering-Plough admits the allegations in first sentence of paragraph 544. Schering-Plough states that the documents cited in paragraph 544 speak for themselves. Schering-Plough denies the remaining allegations of paragraph 544.



545. Schering-Plough states that the document cited in paragraph 545 speaks for itself. Schering-Plough otherwise denies the allegations in paragraph 545.

546. Schering-Plough admits that the West Virginia Attorney General filed suit against Schering-Plough. Schering-Plough avers that the complaint, a writing, speaks for itself.

547-549. The documents referenced in paragraphs 547 through 549 speak for themselves. Schering-Plough denies the remaining allegations in paragraphs 547 through 549.

550-602. The allegations contained in paragraphs 550 through 602 refer to parties other than Schering-Plough. To the extent the allegations contained in paragraphs 550 through 602 are deemed to include allegations against Schering-Plough, Schering-Plough denies the allegations.

603-634. Plaintiff's "Best Price" claims against Schering-Plough have been dismissed by Court Order. Accordingly, no response is required.

635. To the extent that the allegations in paragraph 635 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. Schering-Plough otherwise denies the allegations contained in paragraph 635.

636. To the extent that the allegations in paragraph 636 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. The document cited in paragraph 636 speaks for itself. Schering-Plough otherwise denies the allegations contained in paragraph 636.

637-640. To the extent that the allegations in paragraphs 637 through 640 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. Schering-Plough otherwise denies the allegations contained in paragraphs 637 through 640.

641. Schering-Plough denies the allegations contained in paragraph 641.

642-643. To the extent that the allegations contained in paragraphs 642 through 643 state legal conclusions, no answer is required. To the extent that the allegations in paragraphs 642 through 643 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. Schering-Plough otherwise denies the allegations contained in paragraphs 642 through 643.

644. Schering-Plough denies the allegations contained in paragraph 644.

645. To the extent the allegations in paragraph 645 state legal conclusions, no response is required. Schering-Plough is otherwise without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 645.

646-648. To the extent the allegations in paragraph 646 through 648 state legal conclusions, no response is required. Schering-Plough otherwise denies the allegations contained in paragraphs 646 through 648.

649-650. To the extent that the allegations in paragraphs 649 through 650 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. Schering-Plough otherwise denies the allegations contained in paragraphs 649 through 650.

651. Plaintiff's "Best Price" claims against Schering-Plough have been dismissed by Court Order. Accordingly, no response is required.

652-653. To the extent that the allegations in paragraphs 652 through 653 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations. Schering-Plough otherwise denies the allegations contained in paragraphs 652 through 653.

654. Schering-Plough reasserts and incorporates by reference all preceding paragraphs as though fully set forth herein.

655. Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 655.

656. The allegations in contained paragraph 656 state legal conclusions as to which no answer is required.

657-660. To the extent that the allegations in paragraphs 657 through 660 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraphs 657 through 660. Schering-Plough otherwise denies the allegations in paragraphs 657 through 660.

Schering-Plough denies the allegations contained in the unnumbered paragraph following paragraph 660 and opposes all relief requested therein.

661. Schering-Plough reasserts and incorporates by reference all preceding paragraphs as though fully set forth herein.

662. Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 662.

663. The allegations in contained paragraph 663 state legal conclusions as to which no answer is required.

664-667. To the extent that the allegations in paragraphs 664 through 667 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraphs 664 through 667. Schering-Plough otherwise denies the allegations in paragraphs 664 through 667.

Schering-Plough denies the allegations contained in the unnumbered paragraph following paragraph 667 and opposes all relief requested therein.

668-679. Plaintiff's "Best Price" claims against Schering-Plough have been dismissed by Court Order. Accordingly, no response is required.

680-691. Plaintiff's "Best Price" claims against Schering-Plough have been dismissed by Court Order. Accordingly, no response is required.

692. Schering-Plough reasserts and incorporates by reference all preceding paragraphs as though fully set forth herein.

693. To the extent that the allegations in paragraph 693 refer to parties other than Schering-Plough, Schering-Plough is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 693. Schering-Plough otherwise denies the allegations in paragraph 693.

Schering-Plough denies the allegations contained in the unnumbered paragraph following paragraph 693 and opposes all relief requested therein.

#### **AFFIRMATIVE AND OTHER DEFENSES**

Without assuming the burden of proof of such defenses that it would not otherwise have, Schering-Plough asserts the following defenses:

##### **First Defense**

Plaintiff fails to state a claim against Schering-Plough upon which relief may be granted.

##### **Second Defense**

Some or all of Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

**Third Defense**

Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Schering-Plough as alleged in the Complaint.

**Fourth Defense**

To the extent Plaintiff or any of its citizens for whom it is seeking relief obtains recovery in any other case predicated on the same factual allegations, it is barred from seeking recovery against Schering-Plough based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel and the prohibition on double recovery for the same injury.

**Fifth Defense**

Plaintiff's claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitution of the State of Montana.

**Sixth Defense**

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff or any of its citizens for whom it is seeking relief has released, settled, entered into an accord and satisfaction or otherwise compromised its claims.

**Seventh Defense**

Any and all actions taken by Schering-Plough with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

**Eighth Defense**

Plaintiff's state law claims are preempted, in whole or in part, by federal law, including without limitation, the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

**Ninth Defense**

Plaintiff's claims are preempted by the dormant Commerce Clause of the United States Constitution.

**Tenth Defense**

Plaintiff's claims against Schering-Plough are barred because Schering-Plough has complied with all applicable regulations of the federal and state governments.

**Eleventh Defense**

Plaintiff's claims against Schering-Plough are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel and waiver.

**Twelfth Defense**

Plaintiff's claims are barred, in whole or in part, because they violate Schering-Plough's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Constitution of the State of Montana, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

**Thirteenth Defense**

Schering-Plough's statements or actions were not the proximate cause or cause in fact of any injury or alleged loss.

**Fourteenth Defense**

Plaintiff fails to state with particularity facts to support the fraud allegations, and fails to plead with particularity the fraudulent concealment and multi-source medicine allegations against Schering-Plough contained in the Complaint.

**Fifteenth Defense**

Plaintiff has no standing or capacity to bring some or all of the claims raised in this suit, including but not limited, to Plaintiff's asserted status in *parens patriae* to recover Medicaid or Medicare expenditures or to seek injunctive relief.

**Sixteenth Defense**

Plaintiff fails to allege with particularity its civil conspiracy claims against Schering-Plough as required by FED. R. CIV. P. 9(b).

**Seventeenth Defense**

Plaintiff's claims against Schering-Plough are barred because Schering-Plough did not directly or indirectly conspire with any other entity or engage in any other conduct in violation of state or federal law.

**Eighteenth Defense**

Plaintiff's claims against Schering-Plough are barred, in whole or in part, because Schering-Plough did not make any false statements to Plaintiff or any of the citizens for whom Plaintiff is seeking relief. As to any statement asserted against Schering-Plough that Plaintiff alleges to be false or misleading, Schering-Plough had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

**Nineteenth Defense**

Plaintiff's claims against Schering-Plough are barred because Schering-Plough did not directly or indirectly engage in any conduct in violation of state or federal law.

**Twentieth Defense**

Schering-Plough denies that Plaintiff has valid consumer protection claims against Schering-Plough under Montana state law. However, if such claims are found to exist, Schering-Plough pleads all available defenses under the applicable laws.

**Twenty-First Defense**

Any allegedly fraudulent statements or conduct of Schering-Plough did not directly or proximately cause the alleged injuries as required under state consumer protection laws of Montana.

**Twenty-Second Defense**

Schering-Plough's conduct was not "deceptive" as required under Montana consumer protection laws.

**Twenty-Third Defense**

To the extent that Plaintiff seeks equitable relief against Schering-Plough, Plaintiff is not entitled to such relief because there is an adequate remedy at law.

**Twenty-Fourth Defense**

Plaintiff did not rely on the allegedly fraudulent statements or conduct of Schering-Plough as required under the Montana consumer protection laws.

**Twenty-Fifth Defense**

Any allegedly fraudulent statement or conduct of Schering-Plough was not consumer-oriented as required under the Montana consumer protection laws.

**Twenty-Sixth Defense**

Plaintiff's claims against Schering-Plough for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

**Twenty-Seventh Defense**

Some or all of Plaintiff's claims for injunctive relief against Schering-Plough are barred by the doctrines of *in pari delicto* and/or unclean hands.



**Twenty-Eighth Defense**

Some or all of Plaintiff's claims against Schering-Plough arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligation to set reimbursement rates at Estimated Acquisition Cost.

**Twenty-Ninth Defense**

Plaintiff's claims against Schering-Plough are barred, in whole or in part, due to its failure to join indispensable parties.

**Thirtieth Defense**

Plaintiff's claims against Schering-Plough are barred, in whole or in part, because it suffered no damages as a result of the matters alleged in the Complaint.

**Thirty-First Defense**

Plaintiff's claims are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of its own conduct or the intervening or superseding conduct of third parties.

**Thirty-Second Defense**

Plaintiff's claims against Schering-Plough for damages are barred, in whole or in part, because: (1) Plaintiff failed to mitigate its damages, and that failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Schering-Plough; (2) Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; (3) by the doctrine of consent and/or ratification to the extent that Plaintiff has received and paid for medicines manufactured, marketed and sold by Schering-Plough after the filing of Plaintiff's original Complaint; and (4) Plaintiff's claims are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

**Thirty-Third Defense**

Schering-Plough is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

**Thirty-Fourth Defense**

The applicable statutory ceilings on recoverable damages must limit any damages recovered by Plaintiff from Schering-Plough.

**Thirty-Fifth Defense**

Plaintiff fails to allege facts or a cause of action against Schering-Plough sufficient to support a claim for attorneys' fees, double damages and/or legal fees.

**Thirty-Sixth Defense**

Plaintiff's punitive damages claims against Schering-Plough: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against Schering-Plough; (3) cannot be sustained because laws regarding the standards for determining liability for and the amount of punitive damages fail to give Schering-Plough prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of Schering-Plough's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Constitution of the State of Montana; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate Schering-Plough's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and applicable state laws of Montana; (5) cannot be sustained because an award of punitive damages in this case,

combined with any prior, contemporaneous, or subsequent judgments against Schering-Plough for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Schering-Plough's medicines, would constitute impermissible multiple punishments for the same wrong in violation of Schering-Plough's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law and statutory law of Montana; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Schering-Plough's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and public policies of Montana; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according Schering-Plough the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Schering-Plough's rights guaranteed by the Fourth, Fifth, and Sixth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law and public policies of Montana.

### **Thirty-Seventh Defense**

Plaintiff's claim for punitive damages against Schering-Plough cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the

appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including without limitation, the residence, wealth, and corporate status of Schering-Plough; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding Plaintiff's burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Schering-Plough's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law and public policies of Montana.

### **Thirty-Eighth Defense**

Plaintiff's claim for punitive damages against Schering-Plough cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate Schering-Plough's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate Schering-Plough's right not to be subjected to an excessive award; and (3) be improper under the Constitution, common law and public policies of Montana.

**Thirty-Ninth Defense**

Plaintiff's fraud-based claims and plaintiff's claims of fraudulent concealment are barred because Plaintiff knew or should have known for more than a decade before the filing of the complaint that published AWP's do not represent actual averages of the prices at which providers or pharmacies are able to purchase drugs.

**Fortieth Defense**

Schering-Plough adopts by reference any additional applicable defense pled by any other defendant in this case, not otherwise pled herein.

**Forty-First Defense**

Schering-Plough hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense.

WHEREFORE, Schering-Plough prays that this Court:

1. Dismiss the State of Montana's Second Amended Complaint with prejudice and enter judgment in favor of Schering-Plough and against plaintiff;
2. Award Schering-Plough its costs and expenses; and
3. Grant such other and further relief for Schering-Plough as this Court deems just and proper.

Schering-Plough Corporation  
By their attorneys,

/s/ John T. Montgomery  
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Dated: July 12, 2004

**CERTIFICATE OF SERVICE**

I hereby certify that on July 12, 2004, I caused a true and correct copy of Schering-Plough Corporation's Answer to the State of Montana's Second Amended Complaint to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ John R. Therien

John R. Therien